

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2010, has been entered.
2. Claims 37-62 are pending. Claims 48-50 and 53 have been withdrawn. Claims 37-47, 51, 52 and 54-62 are considered in this Office action.

### ***Claim Objection***

3. **(Prior objection-withdrawn)** The objection to Claim 51, as being dependent on withdrawn Claim 50, **is withdrawn** in view of the amendment to the claim.

### ***Claim Rejections - 35 USC 112***

4. The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. **(Prior rejection-maintained)** The rejection of Claims 37-47, 51, 52 and 54-62 under 35 USC 112, first paragraph, as failing to comply with the written description requirement, **is maintained** for the reason of record.

In response to Applicant's argument:

6. Applicants argue that the functional characteristic of having increased peptide load is dependant on the peptide's alteration of a lowered isoelectric point. This is not merely a functional description but rather an alteration with a specific outcome that can be tested by one skilled in the art using routine techniques. The specification describes a number of ways in which a peptide's isoelectric point can be lowered and one skilled in the art would use methods appropriate for their peptide of choice. Just because a particular sequence with a particular structural modification is not universally specified by the claims, this does not preclude having written description.

7. Applicants' argument is not persuasive because Applicants appear to argue the claimed method is enabled. However, the claims are rejected as failing to comply with the written description requirement, not enablement requirement. In the present case, the claim limitation specifically requires that modification of a peptide's isoelectric point must lead to a specific effect: "wherein at least one of peptide load and solubility of the conjugate consisting of the plurality of the second peptide and carrier protein is increased as compared to a conjugate of a plurality of the first peptide and carrier protein and wherein the second peptide has a non-naturally occurring sequence". However, the specification has shown that there are uncertainties regarding which modified peptide-carrier conjugates would have "increased peptide load and solubility". For example, the specification shows that peptides HA2-22 and HA2-23, which were modified to have lower pI than their parent peptides, actually have lower peptide loads on OMPC carrier protein; see p. 35 and Table VII. Thus, in the limited working examples, the specification has shown that it is uncertain what kind of peptide modification would result in "increased peptide load and solubility". Although the specification shows 5 modified HA peptides (15-21-mers) conjugated to OMPC carrier, the specification lacks sufficient variety of species to reflect the variance of peptide-carrier conjugates encompassed in the scope of the claims. The specification has not established there is nexus between the "lower pI" of peptides and

“increased peptide load and solubility” on all a peptide-carrier conjugate. The specification has provided little guidance how peptides of any kinds with “lower pI” would correlate with their “increased peptide load and solubility” on all carrier proteins in Claim 38. Thus, the claimed method is not adequately described. The rejection is therefore maintained.

***Remarks***

8. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/  
Primary Examiner, Art Unit 1648